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Required Report - public distribution

**Date:** 8/13/2013

**GAIN Report Number:** CI1309

## Chile

### Agricultural Biotechnology Annual

#### Agricultural biotechnology situation in Chile

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**Report Highlights:**

The overall biotech situation in Chile remains the same as last year. Congress is still “debating” proposed rules and regulations but no real movement has resulted.

In May 2013 Congress approved the text of the *International Convention for the Protection of New Varieties of Plants* (1991 version, UPOV-91) and now is working on the implementing regulation before the ratification by the president.

**Section I. Executive Summary:**

**REPORT OUTLINE**

Report Highlights:

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## CHAPTER 2: ANIMAL BIOTECHNOLOGY

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### ***SECTION I. EXECUTIVE SUMMARY:***

Under the current Chilean regulations, Chilean farmers can only propagate transgenic seeds for export. In food products, the Ministry of Health requires that all events be registered. The product must be labeled only if substantially different from the conventional counterpart.

Over eight years ago anti-genetically engineered (GE) groups submitted two anti GE bills to the Chilean Congress that will supposedly regulate biotechnology. One requires mandatory labeling and the other would create a biotechnology regulatory framework. Congress has yet to move forward on either of these bills.

The Piñera Administration, especially the Minister of Agriculture, are seen as enthusiastic to push forward on reviewing the regulations that are stuck in Congress so that Chilean farmers may benefit from this technology. However, as far as progress in the Chilean congress, nothing has happened.

Commercially, Chile could be a producer of transgenic sugar beets, corn, alfalfa, and soybeans (if the salmon industry were to lift its self-imposed ban on the use of biotech feeds). Although not widely publicized, Chile has begun to do landmark research in “orphan” crops (non-bulk commodities), such as pine trees, stone fruit, apples, and grapes. As part of the government’s efforts to increase research and development using funds received from copper mining royalties, the Ministries of Education, Agriculture and Economy have established consortiums for biotech research.

As with many developing countries, the majority of research funds come from the public sector. In 2009 the Government announced a number of programs and affiliations with different universities in the United States, Australia and Canada to favor technology transfer and postgraduate degrees with the purpose of increasing research and development.

### ***SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY:***

## ***CHAPTER 1: PLANT BIOTECHNOLOGY***

### ***PART A: PRODUCTION AND TRADE***

- a) **PRODUCT DEVELOPMENT:** There are no GE plants or crops being developed in Chile that could be commercialized in the next five years.
- b) **COMMERCIAL PRODUCTION:** Chile has propagated GE seeds under strict field controls for re-export for more than a decade.
- c) **EXPORTS:** GE seeds reproduced in Chile are exported primarily to the United States and Canada. The export documentation details the types of seeds and GE events.
- d) **IMPORTS:** Chile imports processed products that contain GE ingredients and GE seeds for reproduction and re-export. Chile imports GE corn and soy animal feed from Brazil and Argentina as well as the United States.
- e) **FOOD AID RECIPIENT COUNTRIES:** Chile is a mayor agricultural export country and does not need food aid.

### ***PART B: POLICY***

#### **a)REGULATORY FRAMEWORK:**

- i. Responsible Government Ministries: Chile does not have a biotechnology framework in place, only the reproduction of seeds to be re-exported is allowed under strict control from the Agricultural and Livestock Service (SAG) of the Ministry of Agriculture, Resolution 1523 from 2001 regulates this process. The registration, approvals of events for human consumption and the labeling of GE products only if they are substantially different to the conventional product is under the Ministry of Health, Decree 115.
- ii. Role of the Biosafety Committee/Authority: Chile does not have a Biosafety Committee at this time.
- iii. Assessment of Political Factors: There have been many comments from this new Administration regarding the need to regulate biotech being that Chilean farmers can not benefit from this technology. The Pinera Administration is business/private sector oriented. Thus they understand the double standard farmers are facing; that they can produce their crops for export, but not use them and at the same time must buy imported animal feed at a higher price. Despite these arguments, the political impact of pushing a bioeafety regulation in an election year, by either side, makes the U.S. Foreign Agriculture Service office in Santiago (FAS/Santiago) believes that there is no chance it will move in the near future.
- iv. Distinctions between Food and Feed Regulations: There are some differences between the regulatory treatments of the approval for food, feed, processing, and environmental release. Food products that

contain GE ingredients are imported without any problems, as is feed. In the case of environmental released, only seed reproduction for re-export is allowed. This is managed under strict supervision from SAG.

v. Pertinent and Pending Legislation: There are three pending legislations in Congress that could potentially affect United States exports to Chile but the legislation has not advanced in years and during the ramp up to an election year (2014), no movement is expected. The legislations are: mandatory labeling requirement (Boletin 3818-11/2005); the biotech framework (Boletin 4690-01/2006) and a ten years moratoria (Boletin 8507-11/2012).

vi. Timelines for Approvals: Discussion for approval in Congress depends on the urgency of the matter, and that urgency is giving by the Presidency. If the legislations doesn't have urgency, they could sit in purgatory for ever; all legislation mentioned on the previous point have not been flagged as urgent and thus it is unlikely that Congress will move on them.

b) APPROVALS: Only the reproduction of seeds for re-export is allowed in Chile. Field trials are allowed but are treated the same way, under strict controls from SAG; there are no crops authorized to be commercialized in the country.

c) FIELD TESTING: Chile allows field trials for new events which are treated the same as the production of seeds, this year was not possible to obtain the official information as it was declare sensitive.

d) STACKED EVENTS: The Ministry of Agriculture treats stacked events in field trials and reproduction of seeds as if it was a single new event. The Ministry of Health, on the other hand, regulates the imports and the domestic production of food products; and requires all events to be registered in the Chile. Although, if the events are registered with U.S. Food and Drug Administration, the process is faster.

e) ADDITIONAL REQUIRMENTS: No additional registration is required beyond approval and prior to use.

f) COEXISTENCE: Resolution 1523 of 2001 introduced a traceability system and documentation requirements for all seeds and the fields where they are planted. As part of the process for every field trial approval, biosafety measures are established, such as physical isolation from sexually compatible species and post harvest management.

g) LABELING: The Ministry of Health only requires labeling of the product when the GE derived ingredient/product is different than the conventional one.

h) TRADE BARRIERS: Until the discussion on the framework to regulate biotechnology-related issues is over, FAS/Santiago cannot say that there are any trade barriers. It will be clearer once the discussion begins since the labeling issue is very sensitive.

i) INTELLECTUAL PROPERTY RIGHTS (IPR): Congress approved the ratification of UPOV 91; it

was ratified by the Constitutional Court and is waiting for the signature of the President. Due to the sensitivity of the issue and due to the fact that this is an election year, FAS/Santiago does not see that there is political will to signing the legislation, despite it being a requirement in the United States - Chile Free Trade Agreement.

The International Union for the Protection of New Varieties of Plants or UPOV (French: *Union internationale pour la protection des obtentions végétales*) is an intergovernmental organization with headquarters in Geneva, Switzerland.

UPOV was established by the International Convention for the Protection of New Varieties of Plants. The Convention was adopted in Paris in 1961 and revised in 1972, 1978 and 1991 (UPOV-91). The objective of the Convention is the protection of new varieties of plants by an intellectual property right. By codifying intellectual property for plant breeders, UPOV aims to encourage the development of new varieties of plants for the benefit of society.

j) CARTAGENA PROTOCOL RATIFICATION: Chile signed the Cartagena Protocol on Biosafety, but has not ratified it yet. There are no visible intentions on ratifying the Protocol in the near future.

k) INTERNATIONAL TREATIES/FORA: As Chile is an agricultural export based economy, with agricultural exports accounting for 15% of GDP; Chile has taken a cautionary approach on biotech issues and play a muted role in international fora. Chile participates in the Asian-Pacific Economic Cooperation (APEC), MERCOSUR (Andean Community), and the Organization for American States. Additionally it participates in United Nations and World Trade Organization entities such as Food and Agriculture Organization, Codex, and the International Plant Protection Convention (IPPC).

l) RELATED ISSUES: Regarding climate change and food security; there is some research being done in Chile, some of them on the universities or by the U.S. companies established in the country on drought resistance, especially on corn. Due to the fact that it is impossible to release them for commercial use the product of the research is taken back to the U.S.

m) MONITORING AND TESTING: There is no official monitoring or testing program for GE products.

n) LOW-LEVEL PRESENCE POLICY (LLP): There is no LLP policy in Chile as it is part of the discussion of the projects in Congress.

### ***PART C: MARKETING***

a) MARKET ACCEPTANCE: The agricultural export sector remains concerned about the trade implications of this technology. They view the issue from the perspective of how will the uses of transgenic affect Chile's "natural" image. They argue that currently there are few benefits for the products in which Chile has a competitive advantage (horticultural crops, salmon and forestry).

b) PUBLIC/PRIVATE OPINIONS: There are many organizations in Chile both against and in favor of this technology and both groups with their followers. FAS/Santiago believes that since the public has

been targeted with incorrect information for so long, many of them believe that GE products are bad for them, the groups against this technology have done a good job providing misleading information and confusing the public. For the groups in favor of the technology, it is difficult to change the opinion of the general public but more of the educated people believe this technology can benefit the country. FAS/Santiago believes that the users should have a bigger role in putting pressure on their representatives to move the regulations in Congress, as these users will see the benefits and are disadvantages from not being able to use the technology

c) **MARKETING STUDIES:** There are no studies on the marketing of GE plants and plant products in Chile.

#### ***PART D: CAPACITY BUILDING AND OUTREACH***

a) **ACTIVITIES:** U.S. Government or U.S. Department of Agriculture (USDA) funded capacity building or outreach activities.

In 2012, using State Department funds, FAS collaborated with the International Life Sciences Institute to have targeted environmental risk and regulatory workshop with the Ministries of Environment and Agriculture in Santiago.

In 2011, FAS in collaboration with Asia Biobusiness, Inter-American Institute for Agricultural Cooperation and the Chilean Ministry of Agriculture organized a two days Risk Communication Workshop that had the participation of all the Ministries that will have to address the public to clarify misleading information, or just speak about biotechnology in general. The Minister of Agriculture, opened the workshop and supported the event.

In 2010, FAS and the State Department organized a seminar focused on how Agricultural Biotechnology can help the region address climate change issues. FAS/Santiago has included Argentina and Peru to make it a regional activity. Two speakers from the United States will participate of this seminar.

FAS/Santiago is requesting a speaker from the Environmental Protection Agency to participate at a UN-Cepal sponsored Carbon Footprint Workshop in September to be held in Chile.

In 2009, with the participation of two U.S. speakers, FAS/Santiago organized a biotechnology workshop focused on the international regulatory framework putting emphasis on the regulations in the United States. This workshop was intended for law makers, universities government and research centers.

Every year USDA funds the participation of several Chilean government officials to different APEC Agricultural Biotechnology related activities. For example:

- Funded the participation of a USDA research scientist as speaker at the Red Bio Agricultural biotechnology Conference organized in Viña del Mar, Chile in 2007.
- Organized a biotechnology/IPR seminar with the participation of high level government officials and agencies, June 7, 2007, that included the participation of Clive James (ISAA) and Karen Hauda (U.S. Patent and Trade Mark Office) as main speakers.
- Sponsor the participation of the one member of the Chilean delegation to the APEC High

Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) held in Canberra, Australia, 2007.

- Embassy Science Fellowship program with the participation of a USDA/Agricultural Research Service scientist for two months in Chile from May-July 2006.
- Ministry of Agriculture Official was sent to a training course in the Philippines in June 2006 on Commercializing biotech crops.
- The U.S. Government participated in the Tenth APEC Research, Development and Extension of Agricultural Biotechnology (RDEAB) hosted by Chile in November 2005,
- FAS/Santiago organized a reverse U.S. congressional delegation to the United States to learn about the U.S. regulatory System for Biotech products in July 2005;
- FAS/Santiago sponsored a Chilean expert to attend the APEC Seminar: “Creating a Positive Investment Environment for Agricultural Biotechnology”, in Malaysia in Dec 04;
- FAS/Santiago organized a panel of experts to address the Chilean Agriculture and Health Committees in Oct 04;
- FAS/Santiago sent the President of the Small Farmers Cooperative Confederation to a farmer-to-farmer training program in Honduras in Aug-Sept 04;
- FAS/Santiago sponsored two participants to attend the Michigan State biotechnology short course in August 2004; FAS/Santiago hosted a visit to the United States of a team of Ministry of Health officials tasked with gathering information about other countries biotech regulations in Mar-Apr 04;
- FAS/Santiago coordinated between the Einstein Institute for Science, Health and the Courts (EINSHAC) and the Chilean Judicial Institute to provide technical training to the judiciary regarding biotechnology in civil, criminal and family cases in Mar 04;
- FAS/Santiago organized the HLPDAB in Chile, in Feb 04 and funded the participation of 22 representatives from APEC emerging markets to attend, as well as nine speakers.

#### b) STRATEGIES AND NEEDS:

FAS/Santiago’s strategies on biotechnology have focused in two main areas over the past 7 years; the regulatory aspect of the issue and the other is providing science based information.

The main objective regarding biotechnology regulation is to have Chile adopt a framework that is science base and that does not impose trade barriers. To accomplish this goal FAS/Santiago has taken congressmen to the United States so they can get knowledge of the regulatory process of biotechnology in the United States. There they met with all the regulatory agencies, non-governmental organizations and growers to have a better understanding of the benefits of this technology so they can better regulate in Chile. One of the participants of the group was a senator that drafted the framework being discussed in Congress, a draft that was shared with FAS/Santiago and therefore with USDA and the U.S. Department of State before it was introduced to Congress.

The idea of the workshop that was done this year had the purpose of giving them a more science base knowledge to regulate accordingly, unfortunately they did not participate.

FAS/Santiago will continue focusing on the necessity that Chile adopts a science base regulatory

framework as this is the key stone to begin trade.

FAS/Santiago has organized and will continue organize biotechnology seminars with universities and researches with the participation of U.S. scientist and speakers; FAS/Santiago believe that the more information FAS/Santiago provide, the better the public will be informed, and fears about biotech products will be eliminated.

## ***CHAPTER 2: ANIMAL BIOTECHNOLOGY***

### ***PART E: PRODUCTION AND TRADE***

- a) **PRODUCT DEVELOPMENT:** No genetically engineered or cloned animals are being used or imported into Chile.
- b) **COMMERCIAL PRODUCTION:** Not applicable
- c) **EXPORTS:** Not applicable
- d) **IMPORTS:** There are no regulations in place to allow imports of any GE or cloned animals.

### ***PART F: POLICY***

- a) **REGULATION:** There is no regulation in place; the projects and discussions in Congress only address plant products, animals are not considered at this time. .

i. Responsible Ministries: FAS/Santiago believes that in regards to genetically engineered or cloned animals the government entities that might have a role will be The Ministry of Health in all issues concerning human health and food safety; the Ministry of Agriculture through its SAG office in issues concerning animal health and the new created Environmental Ministry in issues related to the environment.

ii. Assessment of Political Factors: none at this time

iii. Pending legislation: none at this time

iv: Known Discussions: The issue of GE or cloned animals has not been on the the agenda of public discussion, even at a government level the only concern for the moment are the regarding GE plants. FAS/Santiago believes the discussion will begin after the government addresses the framework for plants.

- b) **LABELING AND TRACEABILITY:** None for GE or cloned animals
- c) **TRADE BARRIERS:** none known.
- d) **INTELLECTUAL PROPERTY RIGHTS (IPR):** none specifically applied to animals.

e) INTERNATIONAL TREATIES/FORA: Chile is not a member of any international organizations that support or oppose GE animals or cloning.

***PART G: MARKETING***

a) MARKET ACCEPTANCE: not applicable

b) PUBLIC/PRIVATE OPINIONS: not applicable

c) MARKET STUDIES: not applicable

***PART H: CAPACITY BUILDING AND OUTREACH***

a) ACTIVITIES: none

b) STRATEGIES AND NEEDS: There is an opportunity for interested parties collaborate on research projects with academia. There is also an opportunity to gather information on public opinion.